

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year)
06 April 1998 (06.04.98)

International application No.
PCT/US97/13321

Applicant's or agent's file reference
5093

International filing date (day/month/year)
23 July 1997 (23.07.97)

Priority date (day/month/year)
24 July 1996 (24.07.96)

Applicant

HICKS, Debra, Linn et al

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
18 February 1998 (18.02.98)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Eugénia Santos

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| Applicant's or agent's file reference | FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. | |
| 5093 | | |
| International application No. | International filing date (day/month/year) | (Earliest) Priority Date (day/month/year) |
| PCT/US 97/ 13321 | 23/07/1997 | 24/07/1996 |
| Applicant | | |
| HELENA LABORATORIES CORPORATION et al. | | |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).

2. ☐ Unity of invention is lacking (see Box II).

3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.

☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ Transcribed by this Authority

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is:

Figure No. - ☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/13321

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12Q1/60

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X | DE 36 40 349 A (AUFENANGER JOHANNES DR) 9 June 1988 see the whole document --- | 1-20 |
| X | DATABASE WPI Section Ch, Week 8404 Derwent Publications Ltd., London, GB; Class B04, AN 84-020095 XP002044526 & JP 58 210 000 A (NIPPON CHEMIPHAR CO) , 7 December 1983 see abstract --- | 1-20 |
| X | EP 0 183 381 A (AMANO PHARMA CO LTD) 4 June 1986 see claims 1,7 --- -/-- | 1-20 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

24 October 1997

Date of mailing of the international search report

05. 11. 97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Cartagena y Abella, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/13321

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X | WO 82 00833 A (BATTELLE INSTITUT E V ;BETZ J (DE)) 18 March 1982 see the whole document --- | 1-20 |
| X | DATABASE WPI Section Ch, Week 8327 Derwent Publications Ltd., London, GB; Class B04, AN 83-702559 XP002044527 & JP 58 089 183 A (AMANO PHARM KK) , 27 May 1983 see abstract ----- | 1-20 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/13321

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|-------------------------------------------|---------------------|----------------------------|---------------------|
| DE 3640349 A | 09-06-88 | NONE | |
| EP 0183381 A | 04-06-86 | JP 1719729 C | 14-12-92 |
| | | JP 4007199 B | 10-02-92 |
| | | JP 61108400 A | 27-05-86 |
| | | DE 3565122 A | 27-10-88 |
| | | US 4892816 A | 09-01-90 |
| WO 8200833 A | 18-03-82 | DE 3032377 A | 01-04-82 |

REC'D 16 OCT 1998

WIPO

PCT

| | | |
|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| Applicant's or agent's file reference 5093 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US97/13321 | International filing date (day/month/year) 23 JULY 1997 | Priority date (day/month/year) 24 JULY 1996 |
| International Patent Classification (IPC) or national classification and IPC INC(6): C12Q 1/60 and US Cl.: 435/11, 19, 26 | | |
| Applicant HELENA LABORATORIES CORPORATION | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Date of submission of the demand 18 FEBRUARY 1998 | Date of completion of this report 25 SEPTEMBER 1998 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer RALPH GITOMER |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-1235 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US97/13321

I. Basis of the report

1. This report has been drawn on the basis of (*Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments*):

☒ the international application as originally filed.

☒ the description, pages 1-11, as originally filed.

pages NONE, filed with the demand.

pages NONE, filed with the letter of _____.

pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-20, as originally filed.

Nos. NONE, as amended under Article 19.

Nos. NONE, filed with the demand.

Nos. NONE, filed with the letter of _____.

Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig NONE, as originally filed.

sheets/fig NONE, filed with the demand.

sheets/fig NONE, filed with the letter of _____.

sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE.

☒ the claims, Nos. NONE.

☒ the drawings, sheets/fig NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US97/13321

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>none</u> | YES |
| | Claims <u>1-20</u> | NO |
| Inventive Step (IS) | Claims <u>none</u> | YES |
| | Claims <u>1-20</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-20</u> | YES |
| | Claims <u>none</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claims 1-20 lack novelty under PCT Article 33(2) as being anticipated by each of Aufenanger, Urata, Akiba, and Akiba.

Aufenanger (DE 3640349) entitled "Measuring Lipoprotein Cholesterol Level" teaches in the abstract, a quantitative determination of cholesterol fractions after electrophoretic separation with cholesterol esterase and cholesterol dehydrogenase with other components.

Urata (JP 58210000) entitled "Determination of Concentration of Lipoprotein Cholesterol" teaches in the abstract, staining lipoprotein cholesterol with cholesterol esterase and dehydrogenase with other components including tricine buffer.

Akiba (EP 0183381) entitled "Method for the Determination of Cholesterol" teaches in the abstract determining cholesterol with cholesterol dehydrogenase and an oxidizing agent with other components.

All the features of the present claims are taught by each of the above references for the same function as claimed.

Claims 4 and 14 lack novelty under PCT Article 33(2) as being anticipated by Akiba.

Akiba (JP 58089183) entitled "Preparation of NAD(P)-Dependent Cholesterol Dehydrogenase" teaches in the abstract, cholesterol dehydrogenase from Nocardia.

All the features of claims 4 and 14 are taught by Akiba for the same function as claimed.

----- NEW CITATIONS -----

NONE

OCT 11 1998

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JEROLD I. SCHNEIDER
DORSEY & WHITNEY LLP.
1330 CONNECTICUT AVENUE, NW
SUITE 200
WASHINGTON D. C. 20026

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

13 OCT 1998

Applicant's or agent's file reference

5093

IMPORTANT NOTIFICATION

International application No.

PCT/US97/13321

International filing date (day/month/year)

23 JULY 1997

Priority Date (day/month/year)

24 JULY 1996

Applicant

HELENA LABORATORIES CORPORATION

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

DOCKETED

10-2798

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

RALPH GITOMER

Telephone No. (703) 308-1235

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

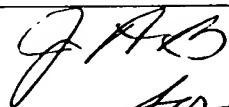

(PCT Article 36 and Rule 70)

| | | |
|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
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| International application No. PCT/US97/13321 | International filing date (day/month/year) 23 JULY 1997 | Priority date (day/month/year) 24 JULY 1996 |
| International Patent Classification (IPC) or national classification and IPC INC(6): C12Q 1/60 and US Cl.: 435/11, 19, 26 | | |
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- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-1235  |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US97/13321

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

☒ the international application as originally filed.

☒ the description, pages 1-11 , as originally filed.

pages NONE , filed with the demand.

pages NONE , filed with the letter of _____.

pages _____ , filed with the letter of _____.

☒ the claims, Nos. 1-20 , as originally filed.

Nos. NONE , as amended under Article 19.

Nos. NONE , filed with the demand.

Nos. NONE , filed with the letter of _____.

Nos. _____ , filed with the letter of _____.

☒ the drawings, sheets/fig NONE , as originally filed.

sheets/fig NONE , filed with the demand.

sheets/fig NONE , filed with the letter of _____.

sheets/fig _____ , filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE .

☒ the claims, Nos. NONE .

☒ the drawings, sheets/fig NONE .

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US97/13321

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>none</u> | YES |
| | Claims <u>1-20</u> | NO |
| Inventive Step (IS) | Claims <u>none</u> | YES |
| | Claims <u>1-20</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-20</u> | YES |
| | Claims <u>none</u> | NO |

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Claims 1-20 lack novelty under PCT Article 33(2) as being anticipated by each of Aufenanger, Urata, Akiba, and Akiba.

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All the features of claims 4 and 14 are taught by Akiba for the same function as claimed.

----- NEW CITATIONS -----
NONE

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (51) International Patent Classification ⁶ : C12Q 1/60 | A1 | (11) International Publication Number: WO 98/03675 (43) International Publication Date: 29 January 1998 (29.01.98) |
| (21) International Application Number: PCT/US97/13321 (22) International Filing Date: 23 July 1997 (23.07.97) (30) Priority Data: 60/022,354 24 July 1996 (24.07.96) US (71) Applicant (for all designated States except US): HELENA LABORATORIES CORPORATION [US/US]; 1530 Lindbergh Drive, P.O. Box 752, Beaumont, TX 77704-0752 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): HICKS, Debra, Linn [US/US]; 4233 Holland Avenue, Orange, TX 77630 (US). MERCHANT, Mark, Edwin [US/US]; 3316 Omaha, Nederland, TX 77627 (US). GUADAGNO, Philip, Angelo [US/US]; 465 Concord, Vidor, TX 77662 (US). ROBINSON, Suzan, Sha [US/US]; 126 Inwood, Silsbee, TX 77656 (US). MILLICAN, Stacey, Eloise [US/US]; 1033 Sunmeadow, Beaumont, TX 77706 (US). NAKAZATO, Tokiya [JP/JP]; 9-21-19, Tokiwa, Urawa-shi, Saitama 336 (JP). (74) Agents: SCHNEIDER, Jerold, I.; Dorsey & Whitney LLP, Suite 200, 1330 Connecticut Avenue N.W., Washington, DC 20036 (US) et al. | | (81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> |
| (54) Title: CHOLESTEROL SEPARATION AND FLUORESCENT ANALYSIS | | |
| (57) Abstract A method and reagent for cholesterol fraction separation by electrophoresis and quantitative interpretation of the HDL, LDL and VLDL fractions. The reagent is applied after the electrophoretic separation and each fraction will fluoresce in response to excitation at a wavelength which peaks at 356nm. The reagent includes NAD (nicotinamide adenine dinucleotide) which, in the reduced form NADH, will fluoresce. | | |

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
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| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
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| DK | Denmark | LK | Sri Lanka | SE | Sweden | | |
| EE | Estonia | LR | Liberia | SG | Singapore | | |